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0001-0102 Rev B



User Manual

PuriCore



Notes

LIMITED WARRANTY STERILOX DENTAL SYSTEM

Includes Sterilox Generator Model #9000-0010 ("Generator"), Sterilox Electrolyte Solution ("Electrolyte") and Sterilox Solution ("Solution," and together with Electrolyte, "Products").

PuriCore hereby warrants that the Products shall, for designated shelf life or use-by date on the label, as applicable, conform in all material respects to the specifications therefore as set forth in documentation accompanying the Products and be free from any material defects in materials and/or workmanship. This limited warranty applies only to Products used in accordance with the Generator User Manual and instructions for the Sterilox Dental System.

PuriCore hereby warrants that the Sterilox Generator shall, for a period of one year from the date of purchase, conform in all material respects to the specifications therefore as set forth in PuriCore's documentation accompanying the product and be free from any material defects in materials and/or workmanship. PuriCore, at its sole discretion, will repair or replace any item covered by this warranty with equivalent units and/or parts.

The aforementioned warranties (collectively, "Warranty") apply solely to the original purchaser and are not transferable.

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This product is covered by Patent No. 7,828,942 and additional pending patents.



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My Sterilox Generator Serial Number:

Introduction

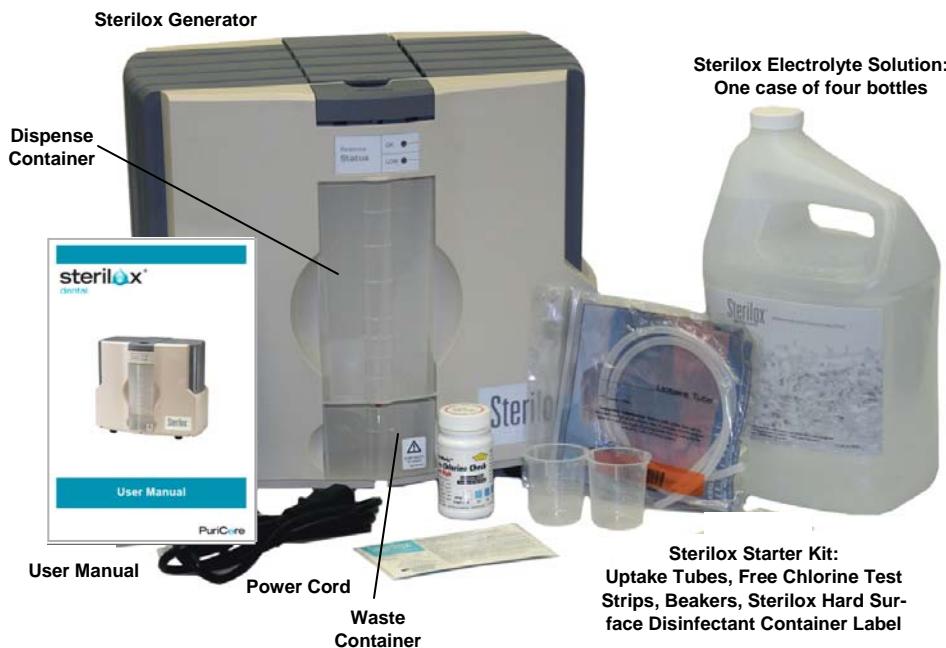
The Sterilox Dental System manufactures a safe, natural, and effective ready-to-use solution formulated as a disinfectant to remove biofilms and harmful pathogens in dental unit water lines (DUWL), as a hospital-grade hard-surface disinfectant, and as an endodontic cleanser following root canal procedures.

The Sterilox Dental System includes the Sterilox Dental Generator, which produces a hypochlorous (HOCl) solution, Sterilox Solution. This solution is non-cytotoxic, non-mutagenic, and has shown no contact hypersensitivity and no oral toxicity.

Shipping Contents

The Sterilox Dental System consists of a Sterilox Dental Generator, the precursor Sterilox Electrolyte Solution, and the Sterilox Starter Kit as shown below.

Sterilox Dental System



Technical Information

Electrical

| | |
|-----------------------------------|------------------------|
| Supply Mains (Nominal) | 100-240V/50-60 Hz |
| Maximum Current..... | 3.5 amps |
| Fuses (2 used: T3.15AH250V) | 3.15A, 250V time delay |
| Supply Voltage Variance | 10% of Nominal |

Environmental

| | |
|--|-----------------------|
| Temperature for Use | Room temperature |
| Storage Temperature (Sterilox Electrolyte Solution)..... | 10°-30° C (50°-85° F) |

Operations

| | |
|----------------|-------------------------------|
| Duty Type..... | Unit can operate continuously |
|----------------|-------------------------------|

Fluid Capacity

| | |
|-------------------------|------------|
| Internal Tank | 4.0 Liters |
| Dispense Container..... | 500ml |
| Waste Container | 150ml |

Physical Characteristics

| | |
|---|--------------------|
| Weight (with no Electrolyte)..... | 5.2 Kg (11.5 lbs.) |
| Weight (with 4.0 liters of Electrolyte) | 9.2 Kg (20.3 lbs.) |
| Height..... | 323 mm (12.7") |
| Width..... | 381 mm (15") |
| Depth | 206 mm (8.11") |

Troubleshooting

PuriCore Customer Service: 800.604.1879

**Have your Sterilox Dental Generator serial number ready
(located on the back cover).**

| Problem | Solution |
|--|---|
| You are missing a part, or the Sterilox Dental Generator is broken. | Call PuriCore Customer Service. |
| The unit fails to power on, which means that none of the lights are illuminated on the Reservoir Status Panel. | Check the fuses. If the fuses are okay, call PuriCore Customer Service. |
| You are out of Sterilox Electrolyte Solution. | Call PuriCore Customer Service to order additional Sterilox Electrolyte Solution. |
| The Sterilox Solution or the Waste Product has spilled in the well(s). | Dry the well(s) with absorbent paper towel. Ensure the containers are installed as described in this User Manual. Empty the waste container regularly. If the Sterilox Generator continues to leak, ensure that the waste extension sleeve is placed properly over the spout. |
| When starting with an empty waste container, the waste container overflows with waste product on a single 500 ml dispense. | Discontinue use immediately and call PuriCore Customer Service. |
| The Sterilox Solution has a very strong chlorine odor. | Test the Sterilox Solution as described on in Operating Procedures in this User Manual. If the AFC level is not within the recommended range, call PuriCore Customer Service. |
| The Sterilox Generator fails to operate. | Turn the Generator off and back on. If the problem continues, call PuriCore Customer Service. |

Introduction

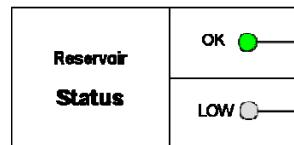
Sterilox Solution Definitions

| | |
|-------------------------------|--|
| Sterilox Electrolyte Solution | The Sterilox Electrolyte Solution is used by the Sterilox Dental Generator to make the Sterilox Solution. The use of any other solution is unauthorized and will void any applicable product warranty. |
| Sterilox Solution | The Sterilox Solution (hypochlorous acid, HOCl) is produced by the Sterilox Dental Generator and is used to disinfect and maintain dental unit water lines, to disinfect hard surfaces, and to cleanse root canals following endodontic procedures. |
| Waste Product | The waste product (dilute sodium hydroxide, NaOH) is produced by the Sterilox Dental Generator and is collected in the waste container in the lower well. This product should be emptied into a sink drain when necessary. The waste product is safe for disposal in drains. |

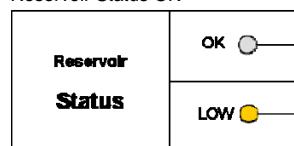
Sterilox Dental Generator Controls

The **Reservoir Status Panel** displays two lights to indicate the level in the Electrolyte reservoir. The green **OK** light indicates that the unit is ready to be used. The yellow **LOW** light indicates that the reservoir requires one bottle of Sterilox Electrolyte Solution. Flashing lights indicate that an error has occurred. Depress and continue to hold down the gray **Dispense Button** to generate Sterilox Solution. Release the Dispense Button to stop the generation of Sterilox Solution. Each time the panel is depress a minimum of 250 ml must be produced to keep the Sterilox Solution within specification.

The **Power Switch** allows you to turn the Generator on or off. The Generator can be left On when not in use.



Reservoir Status OK



Reservoir Status Low



Power switch



Press the Dispense Panel to generate Sterilox Solution.

Installation and Priming

Caution: Read all warning and safety instructions before operating the Sterilox Dental Generator.

1. Unpack the Sterilox Dental Generator

Discard any packing material including any REMOVE BEFORE USE labels and underlying packaging material. Do not apply power to the Sterilox Dental Generator until all packing materials are removed. Remove any rubber caps covering the spouts on the dispense well (top) and the waste well (bottom).

2. Replace the Uptake Tubes

IMPORTANT: The uptake tubes inside the dental unit water bottles must be of medical-grade silicone or neoprene.

If necessary, replace these uptake tubes inside the dental unit water bottles with the uptake tubes provided in the Sterilox Starter Kit.

3. Power On the Generator

Select a level surface on which to operate the Sterilox Dental Generator. The Generator should be positioned for easy access to the rear power switch. Connect the power cord to the back of the Sterilox Dental Generator and plug the other end into an AC power outlet with a grounded receptacle. Press the **ON/OFF switch** on the rear switch to the On position. Observe that the yellow **LOW** light on the **Reservoir Status Panel** is illuminated.

3. Install the Containers

Insert the dispense container in the top well of the Sterilox Dental Generator. Ensure that the waste extension sleeve (1/2-inch clear Teflon tube) is placed over the waste spout. An extra sleeve has been provided for your convenience. Insert the waste container in the bottom well.



Power on the Generator.



Install the sleeve on the waste spout.

Supplies & Accessories

Ordering Sterilox Dental Supplies and Accessories

To order Sterilox Dental supplies, call PuriCore Customer Service at 800.604.1879.

| Item | PuriCore Part Number |
|--|----------------------|
| Sterilox Electrolyte Solution | |
| Case of Four Bottles | 6000-6006 |
| Palintest 1000 Chlorometer-Duo Meter | 3000-3001 |
| Palintest Tablets | 3000-3013 |
| Replacement Waste Spout Sleeve | 5000-5189 |
| Chlorine Test Strips | 6000-6017 |
| Water Bottle Uptake Tubes | 6000-6018 |
| Sterilox Dental Beaker | 6000-6016 |
| Sterilox Hard Surface Disinfectant Container Label | 0001-0142 |

Sterilox Dental Generator Service

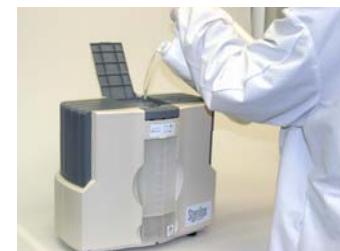
If the Sterilox Dental Generator requires service, follow the instructions below.

1. Call PuriCore Customer Service at 800.604.1879.
2. Have the Sterilox Dental Generator serial number (located on the back cover of the Generator) available to give to the Customer Service Representative.
3. If the PuriCore Customer Service Representative cannot solve the problem over the phone, you will be given instructions on how to return the Sterilox Dental Generator. If the Generator qualifies under the original factory or extended warranty terms and conditions, a replacement unit will be shipped to you at no charge. The replacement Sterilox Dental Generator will have the remaining balance of the original or extended warranty coverage.
4. **It is imperative that the reservoir tank be completely drained before shipping the Sterilox Dental Generator.** Drain the reservoir tank as described in the "Draining the Reservoir Tank" section on page 16 of this User Manual.
5. Place the Sterilox Dental Generator in the original shipping box or in the box provided by PuriCore Customer Service.
6. Return the Sterilox Dental Generator as instructed by the PuriCore Customer Service Representative.

Installation and Priming

4. Fill the Generator with Sterilox Electrolyte Solution

Lift the fill lid on the top of the Sterilox Dental Generator. Carefully and slowly pour an entire bottle of the Sterilox Electrolyte Solution into the funnel. The green **OK** light on the **Reservoir Status Panel** will illuminate. Use caution when pouring the Sterilox Electrolyte Solution to avoid spills.



Fill the Generator with Sterilox Electrolyte Solution.

4. Prime the Generator

The priming process conditions the Sterilox Dental Generator for use and is only needed when it is first unboxed or unused for an extended period. Hold down the Dispense Button and dispense 200 ml of Sterilox Solution into the dispense container.

This initial portion of the Sterilox Solution primes the Generator's electrochemical cell, is not suitable for use, and should be discarded down a sink drain. Dispose of the waste product in the waste container as well. Replace both the dispense container and waste container into their respective wells. **Wait 10 minutes before using the Sterilox Dental Generator again.**



Press the Dispense Button to generate Sterilox Solution for priming.

Note: During the initial priming process the Generator might become unresponsive as the unit initiates itself. Turn the power off and then on to reset the Generator. Repeat the priming procedure two to three times until the Generator no longer becomes unresponsive.

Operating Procedures

Generate Sterilox Solution

Press and continue to hold down the gray dispense button to generate Sterilox Solution. Release the dispense button to stop the generation of Sterilox Solution. Never generate less than 250 ml of the Sterilox Solution to ensure that it is within specification. Use the Sterilox Solution as directed on the following page.

Generate additional Sterilox Solution as required, emptying the waste container when necessary.

Ensure an Adequate Electrolyte Level

If the Sterilox Electrolyte Solution level runs low, the Generator will cease generation of Sterilox Solution, and the yellow **LOW** light on the **Reservoir Status** will be illuminated. Replenish the electrolyte, ensure that the green **OK** light on the **Reservoir Status** is illuminated, and press and continue to hold the gray Dispense Button to complete the generation of Sterilox Solution.

Test the Sterilox Solution

Available Free Chlorine (AFC) Concentration: To test the Sterilox Solution for proper concentration, use one of the two following methods.

- **Free Chlorine Check Test Strips.** When using the test strips, follow the "Directions for Use" provided, which depict the acceptable color range.
- **Palintest 1000 Chlorometer-Duo Meter.** When using the meter, follow the operating procedure provided with the instrument.

The recommended concentration range is 180-260 ppm AFC. Contact PuriCore Customer Service if your Sterilox Solution is out of specification.

To order these test strips or the Palintest meter, see the Supplies and Accessories page in this User Manual.

Maintenance

Replacing the Fuses

The two fuses located on the back of the Sterilox Dental Generator are the only user-serviceable parts.

CAUTION: **Read the fuse label located on the back of the Sterilox Dental Generator before fuse replacement. Replace the fuses only with those of the same type and rating. The Sterilox Dental Generator is protected by two 3.15A, 250V time delay fuses.**

1. Power off the Sterilox Dental Generator and remove the cord.
2. With a small flat screwdriver, open the door to the power entry module, as shown in the upper photo to the right.
3. With the same small flat screwdriver, pull out the fuse holder assembly, as shown in the lower photo to the right.
4. Replace the blown fuses.
5. Reinstall the fuse holder assembly and plug in the power cord. Power on Sterilox Dental Generator and proceed as normal.



Open door of the power entry module



Fuse holder assembly

Maintenance

Draining the Reservoir Tank

If the Sterilox Dental Generator needs to be shipped or transported, you **must** drain the Sterilox Electrolyte Solution as follows.

1. Power off the Sterilox Dental Generator and remove the power cord.
2. Carefully position the Sterilox Dental Generator over the sink.
3. While maintaining the Sterilox Dental Generator in an **upright position**, reach under the bottom of the unit to access the drain plug.
4. With a flat screwdriver, remove the plug by turning the plug head counterclockwise.
5. When the Sterilox Electrolyte Solution stops flowing, *slightly* tip the unit side to side to empty the tank of residual electrolyte solution.
6. When the draining is completed, re-insert the plug into the drain hole and turn it clockwise until fully inserted. Do not over-tighten the plug. Over-tightening the plug can strip the threads and cause the Sterilox Electrolyte Solution to leak when refilling. Always replace the plug immediately after draining the Sterilox Electrolyte Solution.



Remove the plug with a flat screwdriver.



Empty the reservoir tank of all residual Sterilox Electrolyte Solution.

Operating Procedures

WARNING: **For external use only. Not for injection.**

HANDLING: Sterilox Solution is non-irritating and non-sensitizing to skin and eyes and requires no special handling precautions.

STORAGE: Refrigerate unused Sterilox Solution: in a sealed, air-tight plastic or glass container:

Store Sterilox Solution: up to 48 hours

Store Diluted Sterilox Solution for Daily Maintenance: up to 96 hours

INGREDIENTS:

| | |
|-------------------|---------|
| Water | 99.574% |
| Sodium chloride | 0.4% |
| Hypochlorous acid | 0.025% |
| Sodium chlorate | 0.001% |

DISPOSAL: Sterilox Solution is safe to the environment. No special disposal considerations are required for unused Sterilox Solution. Discard any unused refrigerated Sterilox Solution after 48 hours. Discard any unused refrigerated diluted Sterilox Solution for Daily Maintenance after 96 hours.

Sterilox Solution Appearance and Odor

It is normal for the Sterilox Solution to appear slightly cloudy at times. The cloudiness will dissipate in a few minutes. Sterilox Solution will have a mild chlorine odor.

Sterilox Dental Solution Applications

Disinfection of Dental Unit Water Lines

To disinfect dental unit water lines, an initial purging is required followed by daily maintenance as detailed below.

Purging Dental Unit Water Lines

This step is a mandatory initial purge of the dental unit water lines and if line has been inactive for 1 month or more.

1. Ensure that all hand pieces, electric motors, air/water tips, and couplings are removed prior to the primary disinfection of the dental unit water lines.
2. Empty the dental unit water bottle and empty or air dry the lines.
3. Fill the water bottle with the Sterilox Solution.
4. Flush each dental unit water line with approximately 250 ml of Sterilox Solution.

NOTE: Leave a small amount of Sterilox Solution in the bottle. Do not allow the lines to run dry.

5. **Keep the Sterilox Solution in the lines for four hours.**
6. After four hours, air-purge the dental unit water lines until all Sterilox Solution is removed.
7. Refill the dental unit water bottle with Sterilox Solution.
8. Attach the bottle and run a minimum of 250 ml of Sterilox Solution through each of the individual water lines.
9. Air-purge the unit water lines until the Sterilox Solution is removed.
10. Fill the dental unit water bottle with diluted Sterilox Solution for Daily Maintenance (see table below) and flush each line with a minimum of 200 ml.

Daily Maintenance of Dental Unit Water Lines

Use diluted Sterilox Solution for Daily Maintenance every time you refill your dental unit water bottle to keep the water lines free of biofilms buildup. Fill the water bottle with a small volume of Sterilox Solution diluted with water based on the bottle capacity according to the table below.

| Water Bottle Capacity | Add Water to Bottle | Add Sterilox Solution |
|-----------------------|---------------------|-----------------------|
| 750 ml | 735 ml | 15 ml |
| 1000 ml | 980 ml | 20 ml |
| 1500 ml | 1470 ml | 30 ml |
| 2000 ml | 1960 ml | 40 ml |

Maintenance

Warnings: **Always unplug the power cord from the back of the Sterilox Dental Generator before initiating any maintenance procedures to avoid shock or damage to unit.**

Never allow fluid to enter the power entry connection.

Never place a filled Sterilox Dental Generator on its side or upside down.

Cleaning the Sterilox Dental Generator's Exterior

- Always clean the exterior of the Sterilox Dental Generator in its upright position.
- Keep the funnel lid closed while cleaning. Seepage of cleaning solution into the funnel will contaminate the solution in the reservoir tank.
- Remove the dispense and waste containers from the wells of the Sterilox Dental Generator. Wash the containers separately from the Sterilox Dental Generator. Use a solution of mild liquid detergent and warm tap water.
- Do not apply cleaning solution directly to the Sterilox Dental Generator. Slightly dampen a cotton cloth, paper cloth, or sponge with a solution of mild liquid detergent and warm tap water. Clean all exterior surfaces of the Generator. Once cleaned, the surface can be wiped with a dry cloth.

Precautions

General Operating Precautions

- Add Sterilox Electrolyte Solution to the Sterilox Dental Generator **only** when the Sterilox Dental Generator is powered **ON** and the yellow **LOW** light on the **Reservoir Status** is illuminated.
- Always pour the entire contents of the Sterilox Electrolyte Solution bottle into the Generator. The green **OK** light on the **Reservoir Status** indicates that there is enough Sterilox Electrolyte Solution in the reservoir tank.
- Overfilling the Sterilox Electrolyte Solution can damage the electric components of the Sterilox Dental Generator and will void the warranty. Never top-off, overfill the tank, or add Sterilox Electrolyte Solution while the green **OK** light is illuminated.
- Sterilox Electrolyte Solution is not a disinfectant or endodontic cleansing solution.
- Never pour the Sterilox Solution or the Waste Product back into the Generator.

Sterilox Dental Solution Applications

Hospital-Grade Hard Surface Disinfection

The Sterilox Solution is a hospital-grade hard surface disinfectant. Pour full-strength Sterilox Disinfectant Solution into a spray bottle. Apply the disinfectant label provided in the Starter Kit to the exterior of a spray bottle and ensure all staff are properly trained in the use of Sterilox Solution as a hard surface disinfectant.

1. For heavily soiled surfaces, a pre-cleaning step is required.
2. Hold the plastic spray bottle 6-8 inches from the surface to be treated and spray until thoroughly wetted.
3. Allow the surface to remain wet for 5 minutes.
4. Wipe the surface with a clean cloth, sponge, or paper towel.

Endodontic Cleanser

Sterilox Solution is intended for use as an endodontic cleanser following root canal procedures. Dispense Sterilox Solution using a disposable standard dental syringe. The mechanical action of the Sterilox Solution moving in the root canal facilities easy removal of debris and necrotic pulp tissue from the root canal. Use Sterilox Solution to irrigate, cleanse, moisten, lubricate, and debride root canal systems.

1. Fill 12 cc of Sterilox Solution into the recommended standard dental syringe (either two 6-cc syringes or one 12-cc syringe) and attached a standard endodontic needle (approximately 27-30 gauge) to the syringe.
2. Remove the cap from the needle and insert the needle into the root canal.

NOTE: As with any endodontic procedures, use a rubber dam for endodontic therapy and prevent ingestion of the Sterilox Solution. Use personal and patient protection to prevent getting solution in the eyes.

3. Slowly expel the Sterilox Solution from the needle and continuously flush the root canal for 1 minute, working the needle in an up/down motion, being careful not to extend past the root canal apex.
4. Allow 1 ml of Sterilox Solution to remain in the root canal for 5 minutes.
5. Place a hand file of appropriate diameter to working length and mechanically agitate the Solution.
6. Remove the Sterilox Solution by suction.
7. At this step, the clinician may choose to use an appropriate solution to aid smear layer removal.
8. Repeat steps 1-7 at the clinician's discretion.
9. Rinse the canal continuously for 1 minute with Sterilox Solution and dry the canal thoroughly before sealing and obturation.

Precautions

Warnings and Cautions

For your protection, read these safety instructions completely and keep this guide for further reference. Observe and comply with all warnings, cautions, and instructions placed on the Sterilox Dental Generator or described in the installation and operating instructions.

UL Approved: This device has been tested as laboratory equipment in accordance with applicable UL (Underwriters Laboratory) specifications and meets specified electronic leakage requirements.



Warnings: This symbol located on the Sterilox Dental Generator is intended to alert you to a possible electrical shock hazard.

- Use **only** an approved power cord set. If you are not sure as to the proper power cord to use with your Sterilox Dental Generator, contact PuriCore Customer Service.
- Do not operate the Sterilox Dental Generator if there is damage to the power cord or plug, if the Generator is malfunctioning, or if it has been dropped or otherwise damaged. Never attach or detach the Sterilox Dental Generator from a source of AC power with wet hands. **Do not** directly touch or apply power or disconnect power if the power cord is wet. Use a dry glove or towel to avoid a possible shock hazard.
- Never pull on the power cord to remove the plug from an outlet. Grasp the plug and pull to disconnect.
- Do not attempt to service the Sterilox Dental Generator yourself as opening the Generator housing risks a shock hazard that could result in serious injury or death. Opening the Sterilox Dental Generator for any reason will void any applicable product warranty. Contact PuriCore Customer Service to return the Sterilox Dental Generator for repair.
- Do not allow Sterilox Electrolyte Solution to spill over the back of the Generator when filling.

Precautions

Cautions: Be certain to read and understand the important safety and operating information below before proceeding.

- Monitor the waste container levels and dispose the waste product as needed. When disposing the waste product, avoid contact with eyes, skin, mucous membranes, or clothing. Do not allow the waste product to be inhaled or ingested. Wash your hands after handling.
- Sterilox Solution might cause slight discoloration of some unprotected metals such as aluminum and steel. After being thoroughly wetted with Sterilox Solution for 5 minutes, wipe dry with a paper towel, sponge, or cloth.
- Use the Sterilox Dental Generator only as described in this user manual and only with the accessories supplied or recommended by PuriCore.
- **Use only the approved Sterilox Electrolyte Solution.** Use of any other solution can severely damage the Sterilox Dental Generator and will void the warranty.
- Never operate the Sterilox Dental Generator unless both the dispense container and the waste container are inserted into the wells of the Generator.
- Always use the Sterilox Dental Generator on a firm, level surface to ensure against tipping. Do not move the unit when it is filled with fluid unless the Generator is malfunctioning and must be drained. Operate the Generator in an upright position. Placing unit on its side or on its back or front risks spilling of the Sterilox Electrolyte Solution and other damage.